REMARKS

Reconsideration is respectfully requested in view of the foregoing amendments and the remarks which follow.

Claims 7-12, inclusive, have been amended herein and are presently pending before the Examiner.

In order to overcome the claim objections to claim 10, Applicants have amended "..... by weight on the total weight of the composition" to " ....by weight on the total weight of the compositions". Thus, the objection has been overcome and should be withdrawn.

In order to overcome the Examiner's rejection under 35 U.S.C. § 112, second paragraph, Applicants have:

a) inserted the correct dependency of claims 8-12, inclusive; and,

b) in claim 7 inserted after "hyaluronic acid" the wording "or a salt thereof".

In view of the foregoing, the § 112, second paragraph, rejection has been overcome and should be withdrawn.

In order to overcome the rejection under 35 USC§112 first paragraph, Applicants have amended independent claim 7 to cover a therapeutic method for preventing and treating Recurrent Oral Aphthous Ulcers (ROAU or RAU), since, as it clearly results from the same disclosure, the present invention is a method for therapy and prevention of RAU (see the entire specification and also the clinical trials).

This type of pathology having an unknown etiology is also named Recurrent Aphthous Stomatitis (RAS).

The aforementioned clinical trials described in the specification not only demonstrate that hyaluronic acid results in the treatment of ROAU which is **already**

formed, but it also provides effective results in ***preventing*** the formation of ***new ulcers*** of this type (see page 7, lines 13-14).

In fact, as pointed out at page 8, lines 21 - 25 of the specification, it is evident that when compared to a placebo, the administration of the gel composition proved able to reduce the number of ulcers. **This means, therefore, that the gel compositions containing HA resulted in effectively inhibiting the formation of new ulcers.**

In the event the Examiner deems it necessary, Applicants have available and can submit more detailed data concerning this aspect, wherein the results clearly show that the number of patients with new ulcers occurring in the 7 day investigation period was based on **only 29 patients treated with HA versus 48 patients treated with placebo.**

Applicants submit, therefore, that the specification is enabling for a method for both preventing and treating ROAU. Accordingly, the § 112, first paragraph, rejection for non-enablement is deemed to have been overcome. Withdrawal of the rejection is respectfully solicited.

Claims 7-12 have been rejected under 35 U.S.C. § 102(b) over Di Schiena (EP 444492). This rejection is traversed.

Claim 7, as now amended, cannot be said to be anticipated by the clinical trials reported in Di Schiena (EP444492) for the following reasons.

First of all, the clinical trials disclosed in this reference deal with a therapeutic treatment with HA of patients affected by gingivitis and patients who had undergone periodontal surgery.

Gingivitis (see the definition given in the Merck Manual herewith enclosed) is generally caused by bacterial infections, and wounds caused by surgery which are the dental conditions encompassed by Di Schiena. These conditions are completely different from RAS (ROAU), and can in no way be said to be similar or be confused with the RAS or RAU having an unknown etiology, as is clearly pointed out in the chapter, Mouth Sores, of the Merck Manual and enclosed with the instant Office Action.

It follows, therefore, that the invention as claimed in amended claim 7 is novel over Di Schiena and distinguishable therefrom. Since a *prima facie* case of anticipation has not been established, the rejection under § 102(b) has been overcome and should be withdrawn.

The invention as claimed in amended claim 7, besides being new, is also patentable under 35 U.S.C. § 103(a), as implicitly acknowledged by the Examiner when issuing the rejection under 35 U.S. C. §112, first paragraph, (see, in particular page 4, lines 10-12 of the Office Action) as also evidenced by the same Merck Manual.

The issuance a Notice of Allowance is respectfully solicited.

Please charge any fees which may be due and which have not been submitted herewith to our Deposit Account No. 01-0035.

Respectfully submitted,

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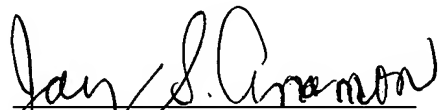
By 
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